§ 25.47

- (d) The Attorney General has exclusive authority to compromise or settle a case under this part during the pendency of any review under §25.42 or of any action to recover penalties and assessments under 31 U.S.C. 3806.
- (e) The investigating official may recommend settlement terms to the reviewing official, the authority head, or the Attorney General, as appropriate. The reviewing official may recommend settlement terms to the authority head, or the Attorney General, as appropriate.
- (f) Any compromise or settlement must be in writing.

§ 25.47 Limitations.

- (a) The notice of hearing with respect to a claim or statement must be served in the manner specified in §25.8 within 6 years after the date on which such claim or statement is made.
- (b) If the respondent fails to file a timely answer, service of a notice under §25.10(b) shall be deemed a notice of hearing for purposes of this section.
- (c) The statute of limitations may be extended by agreement of the parties.

PART 26 [RESERVED]

PART 27—PROTECTION OF HUMAN SUBJECTS

Sec.

27.101 To what does this policy apply?

27.102 Definitions.

27.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

27.104–27.106 [Reserved]

27.107 IRB membership.

27.108 IRB functions and operations.

27.109 IRB review of research.

- 27.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 27.111 Criteria for IRB approval of research.

27.112 Review by institution.

- 27.113 Suspension or termination of IRB approval of research.
- 27.114 Cooperative research.
- 27.115 IRB records.
- 27.116 General requirements for informed consent.
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- 27.118 Applications and proposals lacking definite plans for involvement of human subjects.

- 27.119 Research undertaken without the intention of involving human subjects.
- 27.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

27.121 [Reserved]

27.122 Use of Federal funds.

27.123 Early termination of research support: Evaluation of applications and proposals.

27 124 Conditions

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

SOURCE: 56 FR 28012, 28019, June 18, 1991, unless otherwise noted.

§ 27.101 To what does this policy apply?

- (a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.
- (1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §27.102(e), must comply with all sections of this policy.
- (2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §27.102(e) must be reviewed and approved, in compliance with §27.101, §27.102, and §27.107 through §27.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.
- (b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:
- (1) Research conducted in established or commonly accepted educational settings, involving normal educational